



a Johnson & Johnson company

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McNeil Nutritionals, LLC
317 George Street Suite 500
P.O. Box 2400
New Brunswick, NJ 08903-2400
Tel 732-524-6155

April 5, 2005

Via Fax 301-436-2623
Kathleen Ellwood, Ph.D.
Food and Drug Administration
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Docket 2004P-0294 -- Health Claim Petition to amend 21 CFR §101.80
to authorize a noncariogenicity dental health claim for sucralose

Dear Dr. Ellwood:

In accordance with the provisions of 21 CFR 101.70 (j)(3)(iii), McNeil Nutritionals, LLC, agrees to a six-month extension, until October 7, 2005, of the review process for the above-referenced health claim petition.

Sincerely,

Richard R. Reo
Director, Regulatory Affairs
Phone: 732-524-6774
Fax: 732-524-2189
email: rreo@mnpus.inj.com

cc: Dr. James E. Hoadley

2004P-0294

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